K122689

NOV 7 2012

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: August 31, 2012

Submitter: INO Therapeutics, doing business as Ikaria
2902 Dairy Drive
Madison, Wisconsin 53718

Primary Contact Person: Robert Bovy
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INO Therapeutics/Ikaria
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Director, Regulatory Affairs
INO Therapeutics/Ikaria
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Device Trade Name: INOblender®

Common/Usual Name: Nitric Oxide Administration Apparatus - Back-up System

Classification Names: Apparatus, nitric oxide, backup delivery, Class II – 21 CFR 868.5165

Product Code: MRO

Predicate Device(s): K052663

Device Description: The INOblender provides user set concentrations of inhaled Nitric Oxide (NO), in a balance of nitrogen, mixed into a user settable constant flow of oxygen gas that is being delivered to a patient.

The INOblender is designed to take constant oxygen (0_2) gas flow (5 to 14 L/min) from the integrated O_2 flowmeter and blend in NO at the setting on the NO blender's concentration control dial (5 to 80 ppm). The NO blender is calibrated for cylinder concentrations of 800 ppm NO in a balance of nitrogen (N_2).

Intended Use: The INOblender provides user set concentrations of inhaled Nitric Oxide (NO), in a balance of nitrogen, mixed into a user settable constant flow of oxygen gas that is being delivered to a patient. The intended use for the INOblender is as a back up to a primary nitric oxide delivery system or for short term attended use when a primary delivery device cannot practicably be used. This intended use includes applications within a medical facility and transport outside of a medical facility. The

INOblender is not intended for use as a primary NO delivery system for long-term use.

Technology: All revisions of INOblender® utilize component technology to deliver Nitric Oxide gas to the patient. The components consist of the blender, the regulator and the NO gas tank.

Determination of Substantial Equivalence:

Comparison to Predicate Device:

The INOblender® with modified labeling has the same intended use as the cleared INOblender®. All features are identical except those described in the table below.

Feature / Specification	INOblender- K052663	Modified INOblender
Labeling for compatibility with resuscitators	• Airlife Adult Manual Resuscitator with reservoir tubing • Allegiance ½ L Pediatric Manual Resuscitator with reservoir tubing	• Airlife Adult Manual Resuscitator with reservoir tubing • Allegiance ½ L Pediatric Manual Resuscitator with reservoir tubing • Fisher & Paykel NeoPuff (K892885)

Summary of Non-Clinical Tests:

To confirm compatibility of the INOblender® with the new respiratory care device, this device was set up and calibrated according to the manufacturer's recommendations, and tested using the settings established for the device. The INOblender® was set up according to the manufacturer's recommendations.

The testing concluded four requirements necessary for the operation of the INOblender® and the respiratory care devices to be compatible:

- O_2 dilution
- Effect on respiratory care device
- INOblender® NO dose delivery accuracy
- NO_2 generation

Summary of Clinical Tests:

The subject of this premarket submission, INOblender®, interfaced to the selected respiratory care device, did not require clinical studies to support substantial equivalence.

Conclusion: INO Therapeutics/Ikaria considers the INOblender® to be as safe and as effective as the predicate device, with performance substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 7, 2012

Mr. Robert Bovy
Associate Director, Regulatory Affairs
INO Therapeutics
2902 Dairy Drive
Madison, Wisconsin 53718

Re: K122689
Trade/Device Name: INOblender®
Regulation Number: 21 CFR 868.5165
Regulation Name: Nitric Oxide Administration Apparatus
Regulatory Class: II
Product Code: MRO
Dated: October 18, 2012
Received: October 19, 2012

Dear Mr. Bovy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Digitally signed by Kwame O. Ulmer
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Kwame O. Ulmer, 0.9.2342.19200300.100.1.1=13001836 18
Date: 2012.11.07 15:55:17 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
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Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K122689

Device Name: INOblender®

Indications for Use:

The INOblender provides user set concentrations of inhaled Nitric Oxide (NO), in a balance of nitrogen, mixed into a user settable constant flow of oxygen gas that is being delivered to a patient. The intended use for the INOblender is as a back up to a primary nitric oxide delivery system or for short term attended use when a primary delivery device cannot practicably be used. This intended use includes applications within a medical facility and transport outside of a medical facility. The INOblender is not intended for use as a primary NO delivery system for long-term use.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122689